

September 21,1998

Office of Special Nutritionals (HFS-450) Center for Food Safety and Applied Nutrition Food and Drug Administration 200 C Street, S.W. Washington, D.C. 20204



## NOTIFICATION OF STATEMENTS OF NUTRITIONAL SUPPORT

This notification is filed pursuant to section 403 (r) (6) of the Federal Food, Drug, and Cosmetic Act (FDC Act), 21 U.S.C. Section 343(r)(6).

Name of dietary supplement

FemGard<sup>™</sup>

Statements of nutritional support

With Selenium (as Selenomethionine)

Other ingredients: Vitamine E, Lycopene, Activin(grape seed extract)

Effectiveness of formula documented in the "Journal of National Cancer Institute"

I certify that the information contained in this notice is complete and accurate, and that we have substantiation that the statements are truthful and not misleading.

Shirley L. Gerard

Vice President, CEO

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